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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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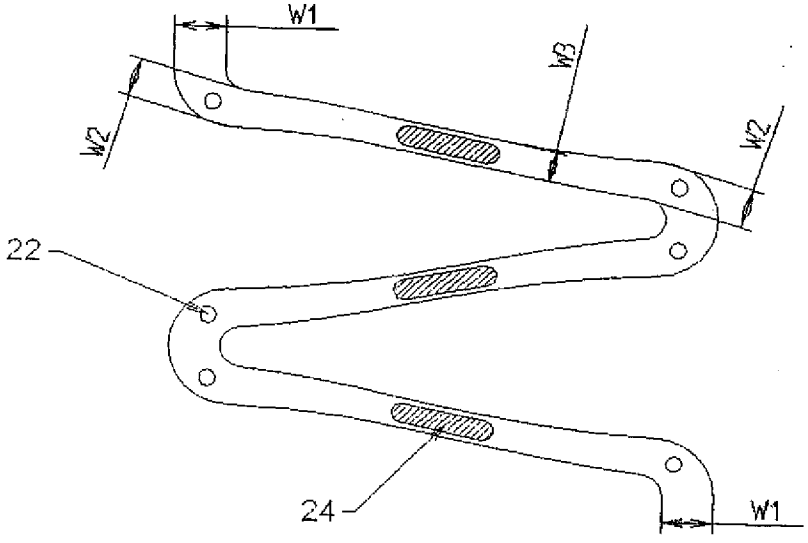
[Continued on next page]

(54) Title: STENTS



(57) Abstract: A stent for implantation into a blood vessel of a patient to maintain the patency of the blood vessel is disclosed. The stent comprises a series of rings (12.1) each composed of bars (16.1, 18.1) arranged zig-zag fashion and joined at their ends by hairpin bends (20.1). The rings are joined by longitudinals. The configuration of the bars and hairpin bends is such that, in the circumferential direction, dimension W3 is less than W2, and dimension W2 is less than W1, which latter dimension is measured in the axial direction. From the larger dimension portion at W2 to the smaller dimension portion at W3, each bar (16.1, 18.1) tapers smoothly without steps or other discontinuities. Recesses or holes (22, 24) can be provided in which drugs can be placed for release into the patient's blood stream.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

STENTS

FIELD OF THE INVENTION

THIS INVENTION relates to stents

BACKGROUND TO THE INVENTION

A stent is used medically in any one of a multiplicity of vessels of the human body to maintain its patency.

Applicant is aware of European patent specifications EP 0 669 114 B1, EP 0 821 920 B1 and EP 0 821 921 A1 and US specifications 6503272, 6342067, 5733303, 5195984, 5102417, 4733665, 6179867, 5514154, 6068656, 6190403, 5913895 and 5643312 which disclose stents of various types. A further stent is disclosed in WO03/007842A1.

Certain studies (such as the ISAR STEREO I and ISAR STEREO II clinical trials) have demonstrated that the thickness of stent struts has a significant influence on clinical outcomes. These studies have shown that reductions in stent strut width and thickness result in statistically significant reductions in neointimal hyperplasia and in-stent restenosis. Thinning down all stent strut dimensions to reduce neointimal hyperplasia also reduces the radial strength of the stent and thus reduces the stents ability to provide sufficient radial support to a diseased, narrowed artery after stent expansion. Furthermore, reducing stent strut thickness has the

effect of reducing the radiopacity or visibility of the stent making delivery and angiographic visualisation post-procedurally (for subsequent angiographic investigations) more difficult.

The studies mentioned above have been published as follows:

- Kastrati A, Mehilli J, Dirschinger J, et al. Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO) trial. Circulation. 2001; 103: 2816–2821.
- Pache J, Kastrati A, Mehilli J, Schuhlen H, Dotzer F, Hausleiter J, Fleckenstein M, Neumann FJ, Sattelberger U, Schmitt C, Muller M, Dirschinger J, Schomig A. Related Articles, Links Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO-2) trial. J Am Coll Cardiol. 2003 Apr 16;41(8):1283-8.

The object of the present invention is to provide a stent which reduces neointimal hyperplasia and restenosis without compromising the radial support provided by the stent to the wall of the vessel that it is in or the visibility of the stent under fluoroscopy.

BRIEF DESCRIPTION OF THE INVENTION

According to one aspect of the present invention there is provided a stent of cylindrical form which comprises a plurality of rings extending around the longitudinal axis of the stent, the rings being spaced apart along the axis and being joined to one another, each ring being of zig-zag form and comprising a plurality of

first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, each bar having end portions contiguous with the hairpin bends and a centre portion which joins said end portions to one another, the bars and hairpin bends having their thickness dimension in the radial direction, characterized in that the width of the centre portion of each bar is less than that of its end portions, and the width of each end portion is less than that of the hairpin bends.

The stent can comprise a metallic substrate and a coating on the metallic substrate, the coating consisting of one or more drugs.

The drug or drugs in the coating can be selected from 2-Methoxyestridiol or its derivatives or prodrugs or Trapidil.

The drug coating is preferably itself coated with a barrier layer of biocompatible polymer. The thickness of the barrier layer can be between 0.01 and 20 microns.

In one form the stent has recesses in which there are drugs for release after implantation. The stent can additionally or alternatively have through holes in which there are drugs for release after implantation.

The stent is preferably of chromium cobalt alloy.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:-

Figure 1 illustrates a known stent in layflat form; and

Figure 2 illustrates, to a larger scale, a detail of a stent according to the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Stents are cut from a metal tube using a techniques such as laser cutting. Use of such a technique is necessary in view of the small dimensions involved and the fineness of the detail required.

The known stent illustrated in Figure 1 comprises a plurality of sections 12 which, in the cylindrical stent, constitute rings which extend around the longitudinal axis of the stent. The stent is shown flat in Figure 1 so that its construction can be seen.

The sections 12 are spaced apart along the longitudinal axis of the stent and are joined to one another by longitudinals 14 which span between one section 12 and an adjacent section 12.

Each section 12 is a zig-zag form and comprises a plurality of first bars 16 all of which are parallel to one another and a plurality of second bars 18 all of which are parallel to one another and at an angle to the bars 16. Bars 16 alternate with bars 18.

The bars are joined to one another by way of hairpin bends 20 which form the connections between adjacent sections 12.

Each longitudinal 14 joins a hairpin bend 20 of one section 12 to a hairpin bend 20 of the adjacent section. In the illustrated example, each longitudinal 14 is of a generally sinusoidal or "S" shaped configuration. As will be seen from Figure 1, some hairpin bends are not joined to opposing hairpin bends.

In Figure 2 two bars 16.1 and 18.1 of the stent are shown to a larger scale. The width of the material of the hairpin bend 20.1 is shown as W1. Adjacent the hairpin bend 20.1 the bars 16.1, 18.1 have a width W2 and at their centres the bars have a width W3. It will be understood that when the cut material is formed into a tube, the dimensions W2 and W3 become the dimensions of the bars in the circumferential direction and W1 a dimension in the axial direction. The relationship between W1, W2 and W3 is such that W1 is greater than W2 which is in turn greater than W3. The change in dimensions from W1 to W2 to W3 is gradual, the change in dimension from W2 to W3 particularly being achieved by tapering the bars from both ends towards their centres.

The configuration shown in Figure 2 minimises stress and/or strain concentrations at the hairpin bends whilst maintaining the requisite high strength in the radial direction and minimising strut width in areas which bear low loads. The ratios of W1 to W2 and W2 to W3 are optimised by a parametric method such as the finite element method in order to minimise peak stresses and strains whilst obtaining adequate strength in the radial direction with minimum bar widths.

Bars and hairpin bends as described reduce the stimuli for restenosis whilst providing adequate vessel support in the radial direction. Adequate visibility under a fluoroscope can be achieved by using radiopaque materials such as chromium cobalt alloy. This alloy is available commercially under the brand names L605, Hayes Alloy 25, Eligloy, Phynox and MP35N.

To provide for delivery of drugs to the implantation site, the bars 16.1, 18.1 are provided with through slots 22 or with recesses 24. If slots 22 are provided these are open at both their radially inner and radially outer ends. If recesses are provided then these are only open at one end and can be in the radially inner surfaces of the bars of the cylindrical stent or in the radially outer surfaces of the bars.

The slots and/or recesses provide reservoirs in which slow release drugs can be placed. The drugs can be in a polymer or other binder or in the form of the pure drug in crystalline form. More, or larger, slots and recesses can be provided where there is a need for greater drug elution. Generally greater drug

elution is required at the axial ends of the stent.

Suitable drugs are Methoxyestridiol or any of its derivatives or pro-drugs and Trapidil.

It is also possible to coat the stent with a drug layer by use of a method such as plasma deposition, vapour deposition, ion deposition, ion beam splutter, spluttering or thermal spraying. The drug coating can itself be covered by a biocompatible polymer. Such polymers are commercially available under the names Pursil, ElastEon or Parylene and provide a diffusion barrier. The thickness of the barrier can be from 0.01 microns and 20 microns to provide for a desired rate of drug release.

CLAIMS:

1. A stent of cylindrical form which comprises a plurality of rings extending around the longitudinal axis of the stent, the rings being spaced apart along the axis and being joined to one another, each ring being of zig-zag form and comprising a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, each bar having end portions contiguous with the hairpin bends and a centre portion which joins said end portions to one another, the bars and hairpin bends having their thickness dimension in the radial direction, characterized in that the width of the centre portion of each bar is less than that of its end portions, and the width of each end portion is less than that of the hairpin bends.

2. A stent as claimed in claim 1, and which comprises a metallic substrate and a coating on the metallic substrate, the coating consisting of one or more drugs.

3. A stent as claimed in claim 2, wherein the drug or drugs in said coating are selected from 2-Methoxyestridiol or its derivatives or prodrugs or Trapidil.

4. A stent as claimed in claim 3, wherein said drug coating is itself coated with a barrier layer of biocompatible polymer.

5. A stent as claimed in claim 4, wherein the thickness of the barrier layer is between 0.01 and 20 microns.

6. A stent as claimed in claim 1 and which has recesses in which there are drugs for release after implantation.

7. A stent as claimed in claim 1 or in claim 6 and which has through holes in which there are drugs for release after implantation.

8. A stent as claimed in any preceding claim and which is of chromium cobalt alloy.

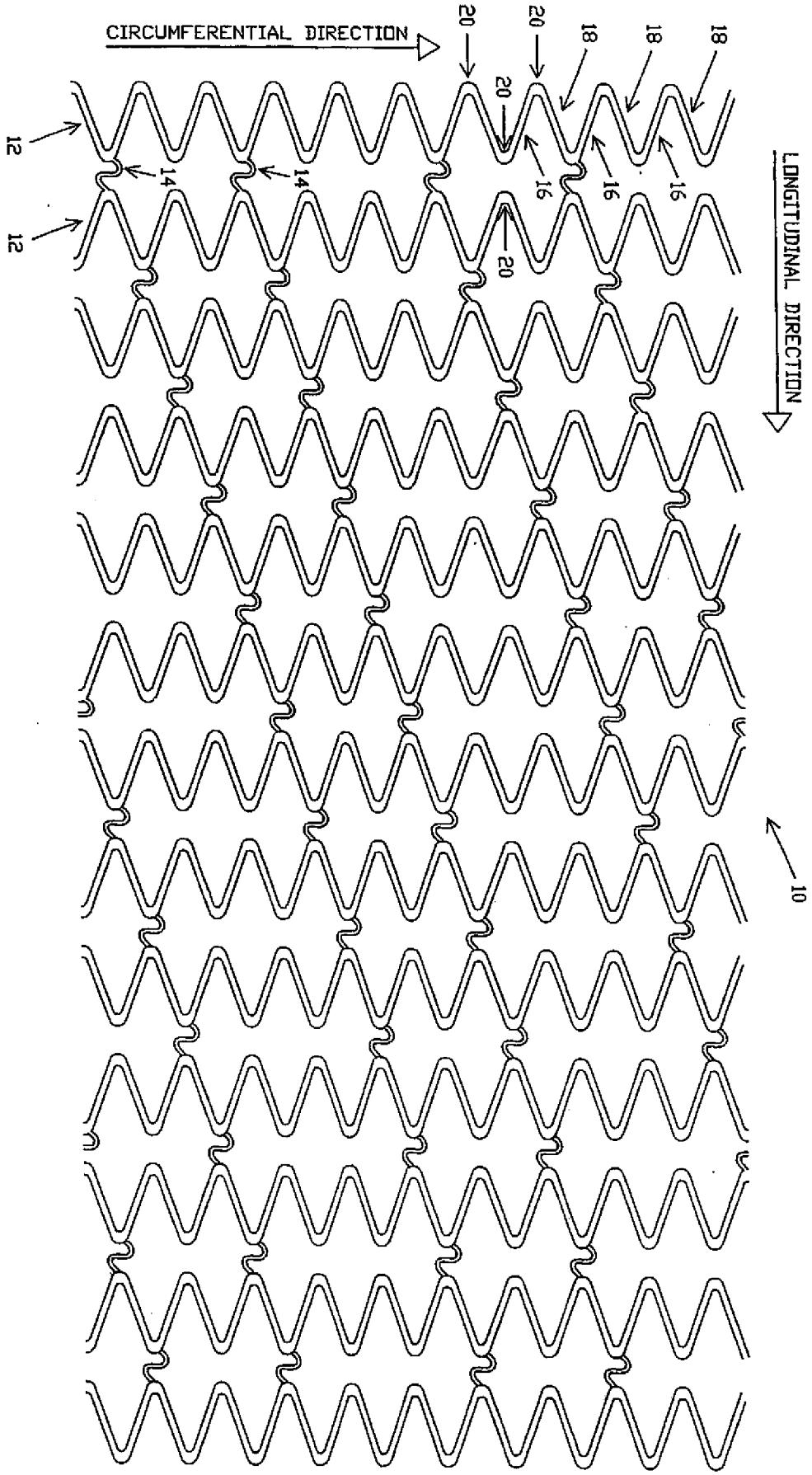
CIRCUMFERENTIAL DIRECTION
LONGITUDINAL DIRECTION
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FIG. 1

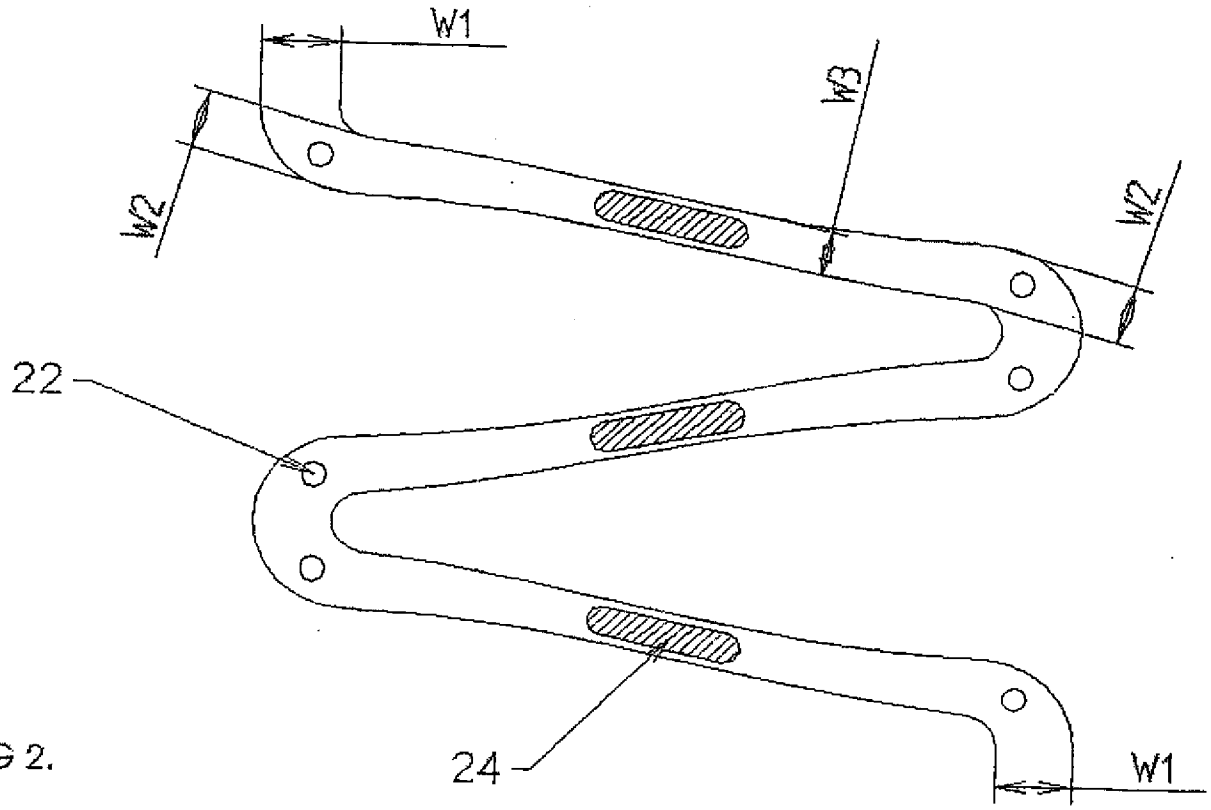

FIG 2.

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(74) Agent: BACON, Brian; Brian Bacon & Associates, 2nd floor, Mariendahl House, Newlands on Main, Main Road, 7700 Newlands (ZA).

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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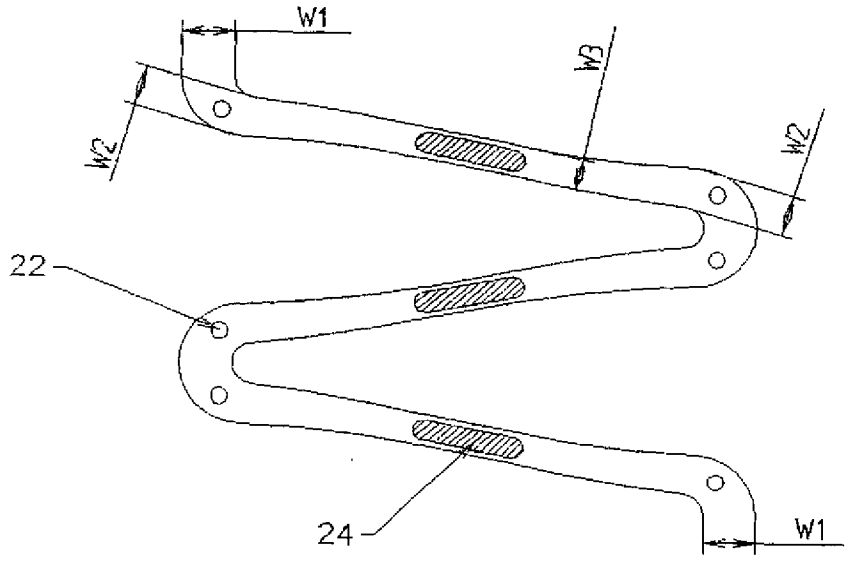
(54) Title: STENTS



(57) Abstract: A stent for implantation into a blood vessel of a patient to maintain the patency of the blood vessel is disclosed. The stent comprises a series of rings (12.1) each composed of bars (16.1, 18.1) arranged zig-zag fashion and joined at their ends by hairpin bends (20.1). The rings are joined by longitudinals. The configuration of the bars and hairpin bends is such that, in the circumferential direction, dimension W3 is less than W2, and dimension W2 is less than W1, which latter dimension is measured in the axial direction. From the larger dimension portion at W2 to the smaller dimension portion at W3, each bar (16.1, 18.1) tapers smoothly without steps or other discontinuities. Recesses or holes (22, 24) can be provided in which drugs can be placed for release into the patient's blood stream.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/ZA2004/000035

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 02/24111 A (CORDIS CORP) 28 March 2002 (2002-03-28) page 19, paragraph FIRST page 4, line 8 - line 9 page 22, last paragraph - page 23, paragraph FIRST claims 20-26 figure 6 _____	1,2,8 3-7
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 August 2004	07/09/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Int[illegible]tional Application No
PCT/ZA2004/000035

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (January 2004)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3,8

A drug coated cylindrical stent made of chromium cobalt alloy comprising a plurality of rings extending around the longitudinal axis of the stent, each comprising an alternate sequence of first bars, hairpins and second bars where the width of the centre portion of each bar is less than that of its end portions and the width of each end portion is less than that of the hairpin bends. The drug or drugs are selected from 2-Methoxyestridiol or its derivatives or prodrugs or Trapidil

1.1. claims: 4,5

A cylindrical stent having a second coating of a biocompatible polymer over a first drug coating

1.2. claims: 6,7

A cylindrical stent comprising recesses or holes where a drug is deposited to be released after implantation

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INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/ZA2004/000035

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

nformation on patent family members

Int[illegible]ional Application No
PCT/ZA2004/000035

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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